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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,474	01/05/2006	Erik Rytter Ottosen	3893-0220PUS2	1370

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BIRCH STEWART KOLASCH & BIRCH  
PO BOX 747  
FALLS CHURCH, VA 22040-0747

EXAMINER
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KOSACK, JOSEPH R

ART UNIT	PAPER NUMBER
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1626

NOTIFICATION DATE	DELIVERY MODE
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08/04/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/563,474	<b>Applicant(s)</b> OTTOSEN ET AL.	
	<b>Examiner</b> Joseph R. Kosack	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 49,63-71,77,78,80,81,83,88,89,91 and 92 is/are pending in the application.
- 4a) Of the above claim(s) 83,88,89 and 92 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 49,50,63-71,77-81 and 91 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 49, 63-71, 77, 78, 80, 81, 83, 88, 89, 91, and 92 are pending in the instant application.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 9, 2010 has been entered.

The request for an interview is noted, but as the instant application is the next application to be worked on by the Examiner, the Applicant has not yet phoned the Examiner to set up the interview as stated in the reply, and the Applicant has not requested a suspension in the instant application, the interview will be conducted after the instant Office action is mailed.

#### ***Previous Claim Rejections - 35 USC § 103***

Claims 49, 63-65, 67, 69-71, 77, 78, 81, and 91 were previously rejected under 35 U.S.C. 103(a) as being unpatentable over Ottosen et al. (WO 2001/05744) in view of Revesz (WO 2002/76447).

The Applicant's arguments have been considered, but were not found to be persuasive because both Ottosen et al. and Revesz teach TNF alpha inhibitors and IL-B. Ottosen et al. teach the template for the tricyclic core, the R2 substitution, the placement of the R3 and R4

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groups, and the other requirements for the compounds that are in the claims. Revesz teaches compounds that have the same tricyclic core, have fluorine for the R3 and R4 groups in the appropriate position, and all the other substituents other than the R2 groups. Additionally, the results provided so far are not sufficient to overcome the extremely strong *prima facie* case of obviousness. Therefore, the rejection must currently be maintained.

### ***Previous Double Patenting Rejections***

Claims 49, 50, 63-71, 77-81 and 91 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,541,670 in view of Revesz (WO 2002/76447).

The rejection is traversed on essentially the same grounds as the 35 U.S.C. 103(a) rejection, which was not found to be persuasive. The rejection is maintained

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

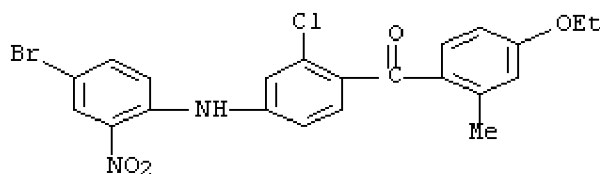
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 49, 63-65, 67, 69-71, 77, 78, 81, and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ottosen et al. (WO 2001/05744) in view of Revesz (WO 2002/76447)

Determination of the scope and content of the prior art (MPEP §2141.01)

Ottosen et al. teaches a compound of the formula



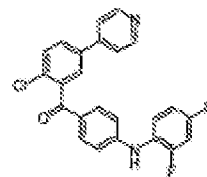
which corresponds to Formula I where R1 is methyl, R2 is chlro, there are two R3s and they are nitro and bromo, R4 is hydrogen, R5 is hydrogen, R6 is Y2-R9, Y2 is O, R9 is methyl substituted by 1 R7, and R7 is methyl. See Example 9, page 23.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

Ottosen et al. does not teach where R3 and R4 is fluorine where R3 is meta to R4 and para to the NH group.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

Revesz teaches various TNF alpha and IL1 beta inhibitors that have the desired three



phenyl ring structure and the motif of the R3 and R4 groups such as . See Example 3, page 14.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to synthesize the compound of Ottosen et al. and modify the R3 and R4 groups with the fluorine atoms of Revesz with a reasonable expectation of success. The motivation to make the claimed invention from the teachings of the prior art is provided by Revesz as Revesz teaches that the 2,4-difluorophenyl group is the especially preferred embodiment. See page 3, lines 13-14.

### ***Double Patenting***

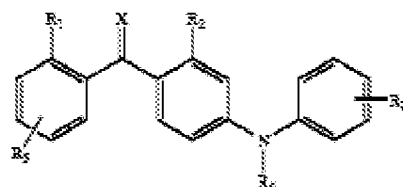
The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 49, 50, 63-71, 77-81 and 91 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,541,670 in view of Revesz (WO 2002/76447). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to the same art specific subject matter.

Determination of the scope and content of the prior art (MPEP §2141.01)



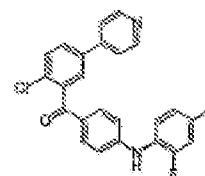
'670 teaches a genus of compounds of the formula which overlaps with the instant claims where R4 is hydrogen, 1 or more R3 groups are fluorine with one at the 2-position, R5 can be amide, and all other substituents are as defined.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

'670 does not teach specifically in the claims where R3 and R4 is fluorine where R3 is meta to R4 and para to the NH group.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

Revesz teaches various TNF alpha and IL1 beta inhibitors that have the desired three



phenyl ring structure and the motif of the R3 and R4 groups such as . See Example 3, page 14.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to synthesize the compound of '670 and modify the R3 and R4 groups with the fluorine atoms of Revesz with a reasonable expectation of success. The motivation to make the claimed invention from the teachings of the prior art is provided by Revesz as Revesz teaches that the 2,4-difluorophenyl group is the especially preferred embodiment. See page 3, lines 13-14.

### ***Conclusion***

Claims 49, 50, 63-71, 77-81 and 91 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph R. Kosack whose telephone number is (571)272-5575. The examiner can normally be reached on M-Th 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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/Joseph R Kosack/  
Primary Examiner, Art Unit 1626